NOV 1 3 2001

SUMMARY

Submitted by: Mr Robert Shaw.
Vice President.
Owen Mumford Incorporated.
1755 – A West Oak Commons Court.
Marietta.
Georgia 30062.
USA.

Tel: 770 977-2226.
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Device Name: Autoject 2.
Classification Name: Syringe Needle Introducers
Predicate Device: Autoject 2 (K945660)

Owen Mumford Limited has been successfully marketing syringe needle introducers throughout the world since 1986.

These products provide a safe and simple way to aid the patient in the home with a recommended treatment regime via a user administered semi-automatic injection.

Device Description.

The Autoject 2 O.T.C is a hand held non-sterile semi-automatic device using pre-filled 1ml glass syringes capable of a subcutaneous injection of FDA approved drugs.

The devices are designed for re-usable use to aid and support patient/ care-giver use in the home with a treatment regime.

The device contains a number of features, which adds to its safety and effectiveness as described under section 1 of this O.T.C application.

Intended Use.

The device is intended for a user administered semi-automatic injection of FDA approved drugs for use in the home by the patient or care-giver.

Operational.

The design concepts of the Autoject 2 submitted in this O.T.C application are such that it makes the principle safe and effective and user friendly in its function and is simply a later model of the current approved Autoject 2 (K945567).

Performance.

A number of tests have been performed proving the correct action of a wide range of functions for this O.T.C application, they are as follows:-

- 1 Meter Drop Test.
- Force to Load.
- Force to Fire.
- Force to Remove RNS.
- Force to Adjust Depth Adjuster.
- Load and Fire Test.
- Dry Firing.
- Environmental Test.
- Dose Efficiency Testing.

Additional tests have been performed in support of this O.T.C application to show that the Autoject 2 is capable of handling a variety of drugs. This is detailed under section 6 of this OTC application.

User Trials.

The correspondence included under section 9 of this over-the-counter submission clearly indicates the success of the device for patient/ care-giver preference as part of a recommended treatment regime.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Robert Shaw
Vice President
Owen Mumford USA, Incorporated
1755-A West Oak Commons Court
Marietta, Georgia 30062

Re: K013362
Trade/Device Name: Autoject 2
Regulation Number: 880.6920
Regulation Name: Syringe Needle Introducer
Regulatory Class: II
Product Code: KZH
Dated: August 31, 2001
Received: October 10,2001

Dear Mr. Shaw:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K013362

INTENDED USE.

NOV 13 2001

Unknown.

510(k) Number:.....

Autoject 2 for O.T.C.

Device Name:.....

Indications for Use.

The Autoject 2 is a hand held mechanical device intended for a self-administered automated subcutaneous injection of FDA approved drugs.

The device is designed for use with a 1ml glass fixed needle syringe, for use in the home by the patient or care-giver to aid and support a recommended treatment regime.

Please do not write below this line – Continue on another page if necessary.

Concurrence of the CDRH, Office of Evaluation (ODE).

Prescription Use:..... ✓ **Over-the –Counter Use:**.....
(per 21 CFR 801.109)

Patricia Cusenza

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K013362